

MAY 21 2010

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

MSDI-1006/PC767.01

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on May 18, 2010

Signature

Typed or printed name Brad A. Schepers

Application Number

10/695,068

Filed

October 28, 2003

First Named Inventor

Young et al.

Art Unit

3733

Examiner

Steven J. Cotronico

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- applicant/inventor.
- assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)
- attorney or agent of record. 45,431
Registration number _____
- attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

Brad A. Schepers

Typed or printed name

(317) 238-6334

Telephone number

May 18, 2010

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.



*Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:) Before the Examiner:
Young et al.) Steven J. Cotroneo
)
Application Serial No. 10/695,068) Group Art Unit: 3733
)
Filed: October 28, 2003) Atty. Ref. No.:
) MSDI-1006/PC767.01
MULTI-AXIAL, CROSS-LINK CONNECTOR)
SYSTEM FOR SPINAL IMPLANTS) May 18, 2010

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the final Office Action dated February 18, 2010, please consider the following. A Notice of Appeal and form a Pre-Appeal Brief Request for Review are submitted herewith along with the requisite appeal fee of \$540 under 37 CFR 41.20(b)(1). No extensions of time or additional fees are believed to be due with regard to the filing of the Notice of Appeal and the Pre-Appeal Brief Request for Review. However, please provide any further extensions of time and charge any additional fees which may be necessary to Deposit Account No. 12-2424, but not to include any payment of issue/publication fees.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:
May 18, 2010
_____ Date of Deposit
Brad A. Schepers
_____ Name of Registered Representative
<i>Brad Schepers</i>
_____ Signature
May 18, 2010
_____ Date of Signature

The final Office Action dated February 18, 2010 rejected claims 1, 2, 4, 10-16, 21, 31, 32 and 34-36 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,136,003 to Van Hoeck et al. in view of U.S. Patent Publication No. 2001/0020168 to Hermann et al., rejected claims 3 and 5 under 35 U.S.C. §103(a) as being unpatentable over the Van Hoeck/Hermann combination in further view of U.S. Patent No. 6,238,396 to Lombardo, and rejected claims 7, 8, 17, 18, 33, 37 and 38 under 35 U.S.C. §103(a) as being unpatentable over the Van Hoeck/Hermann combination in further view of U.S. Patent No. 5,980,523 to Jackson.

Independent claim 1 recites, among other elements and features, “a second hook . . . comprising a second internal surface having a curved portion including a raised ridge extending along said curved portion in a direction from the first end to the second end . . .” Van Hoeck discloses a connector 20 including a pair of oppositely positioned engaging portions 25, 26, each of which includes a receptacle 36 and a fixation surface 33. The final Office Action acknowledges that Van Hoeck fails to disclose a ridge extending along a curved portion, but asserts that Hermann discloses this feature and that “[i]t would have been obvious . . . to modify the device of Hoeck et al. with a ridge extending along the curved portion . . . in order to diminish the friction between the rod and the hook.” (See pg. 3, ll. 3-4 and pg. 4, ll. 1-6).

Hermann discloses a hook 12 that includes a hook element 16 and a shackle element 18. The shackle element 18 includes a groove with a groove bottom 18.1 and two lateral walls 18.2, 18.3. (See ¶ [0042]). The shackle element 18 is formed by drilling a bore through a piece, and then milling a slit extending from the bore to form the lateral walls 18.2, 18.3. (See ¶ [0045]). Additionally, between drilling the bore and milling the slit, a plurality of rills 19 are machined along the surface of the bore. (See ¶ [0046]). As would be appreciated by those skilled in the art, the rills 19 are recessed within the internal surface of the bore. Indeed, Figure 2E of Hermann clearly illustrates this arrangement. Despite this arrangement, the final Office Action asserts that “[t]he rills in the final machined device are raised relative to the base of the device. The process by which the ridges are formed do not negate them from [sic] being raised ridges relative to the bottom of the channel”. (See pg. 6). The Appellant respectfully traverses these assertions. Notably, the rills 19 extend into the groove base 18.1 of the shackle element 18, and are not raised relative to the groove bottom 18.1. Moreover, machining the rills 19 into the groove bottom 18.1 clearly prevents the rills from being raised relative to the groove bottom 18.1.

Hermann is also replete with indications which teach that the rills 19 are not raised relative to the groove bottom 18.1. For example, Hermann indicates that the rills 19 eliminate or diminish friction between the shackle element 18 and the rod 10. (See ¶ [0046]). As would be appreciated by those skilled in the art, if the rills 19 were raised they would increase friction between the shackle element 18 and the rod 10, not reduce friction as specifically taught by Hermann. In discussing related prior art, Hermann indicates that the creation of abrasion particles between a rod and a connecting member can be problematic and **must be prevented**. (See ¶¶ [0006]-[0008]). As would be appreciated by those skilled in the art, having the rills 19 raised relative to the groove bottom 18.1 would likely create abrasion particles between the rod 10 and the shackle element 18, which would not prevent the creation of abrasion particles, as specifically taught by Hermann. Additionally, Hermann indicates that the shackle element 18 provides a clamping force that acts along a considerable surface “so that large point-like stresses which might lead to fissures are avoided”. (See ¶ [0016]). Once again, this aspect of the shackle element 18 undermines any notion that the rills 19 are raised relative to the groove bottom 18.1 since such an arrangement would create point-like stresses. Accordingly, Hermann clearly does not disclose a raised ridge. The subject matter of independent claim 1, as whole, is not accounted for by the Van Hoeck/Hermann combination, and independent claim 1 is submitted to be patentable for at least this reason.

Independent claim 13 recites, among other elements and features, “a second hook . . . comprising a second internal surface wherein the second internal surface curves both in a first direction from the shaft to the second end and in a second direction oblique to the first direction, wherein said curves in said first and second directions are overlapping and intersecting . . . ” With regard to this arrangement, the final Office Action provides an enlarged image of Figure 2E of Hermann and asserts that the rills 19 include first and second surfaces that converge at a ridge, and that the first and second surfaces are curved with respect to the curve of the channel and are oblique based on their angle of approach to the ridge. (See pg. 7). The Appellant respectfully traverses these assertions. The apparatus of independent claim 13 includes a single surface that curves in two directions. The groove bottom 18.1 of the shackle element 18 is curved, at most, in a single direction. Similarly, the rills 19 formed in the groove bottom 18.1 also curve in this single direction. Moreover, the first and second surfaces illustrated on pg. 4 of the final Office

Action are linear, and do not curve in a second direction, let alone a direction that is oblique to the single direction in which the groove bottom 18.1 curves. Accordingly, the subject matter of independent claim 13 has not been accounted for, and independent claim 13 is therefore submitted to be patentable over the cited references.

Independent claim 33 recites, among other features and elements, “wherein said first elongated support rod is locked in contact with said first internal surface of said first hook portion, and said second elongated support rod is locked in contact with said saddle, said first elongated support rod and said second elongated support rod being non-parallel”. The final Office Action acknowledges that the Van Hoeck/Hermann combination does not disclose this arrangement, but asserts that Jackson discloses a system where the spinal rods are positioned to lie non-parallel to each other and not in the same plane, and that it would have been obvious “to have constructed the device of Hoeck et al. . . . with the spinal rods being positioned to lie non-parallel and non-planar to one another”. (See pg. 6, ll. 10-13). Jackson discloses a variety of transverse connectors “which can accommodate variations in the divergence and skew of the spinal rods”. (See Abstract). For example, one connection system 1 includes a base connector 10 that has a cylindrical bore 13 and a boss 14 in communication with the bore 13. The system 1 also includes a hooked rotating connector 32 having an end that may be positioned in the bore 13 such that the connector 32 is rotationally and axially movable relative to the base connector 10. (See col. 5, ll. 4-12). Moreover, Jackson teaches that rotational and axial movement of the connector 32 relative to the connector 10 facilitates use of the system 1 with spinal rods that are skewed relative to one another, as illustrated in Figs. 4 and 25. (See col. 5, ll. 37-46).

The arrangement of the multi-component system 52 illustrated in Figure 2 of Jackson is necessary for its use with non-parallel spinal rods. Thus, in order to achieve the arrangement described in Jackson, where the spinal rods 2 and 3 are non-parallel or skewed relative to one another, the Van Hoeck device would have to be modified to include multiple components that are rotationally and/or axially movable relative to one another. In contrast to this arrangement, the apparatus of independent claim 33 includes a one-piece connector that includes no internal cavity. Similarly, if those skilled in the art were to modify the connector 20 of Van Hoeck in view of Jackson to facilitate its use with spinal rods that are positioned to lie non-parallel with

each other, they would not arrive at the apparatus recited in independent claim 33. Instead, a multi-piece connector that includes at least one internal cavity would be provided.

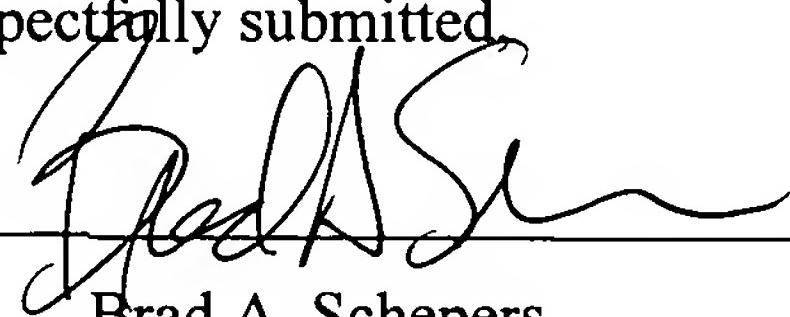
Notwithstanding the foregoing, the final Office Action asserts that Jackson “teaches making a connector to enable a non-parallel alignment [but] does not necessarily lead to a multi-part connector. The Van Hoeck connector can be bent to be non-parallel and enable the teaching of Jackson to form a non-parallel connector”. (See pg. 7). These assertions are respectfully traversed. As an initial matter, while Jackson may arguably generally disclose connectors that accommodate non-parallel rods, it does not disclose any embodiment of a connector for doing so that does not include multiple components. Indeed, Jackson appears to disclose a preference for multi-component connectors so variations in the alignment of the rods will be readily permitted. (See col. 1, ll. 33-36). Likewise, the teachings of Jackson only lead to the use of multi-component connectors in order to accommodate non-parallel rods. As a corollary, the teachings of Jackson have been improperly overstated in the final Office Action, and modifying Van Hoeck in order to accommodate non-parallel rods in view of Jackson would clearly not involve a one-piece connector, as specifically recited in independent claim 33.

Jackson also appears to teach that straight connectors cannot be bent to the most suitable configuration for joining rods that are not parallel (see col. 1, ll. 20-29), which clearly undermines and is incongruent with any notion that the Van Hoeck connector can be bent in the manner asserted in the final Office Action. Similarly, the final Office Action has not provided any support for its assertion that the Van Hoeck connector can be bent to a non-parallel configuration to enable the broad teaching of Jackson without relying on multiple components. The Applicant therefore submits that this assertion has been made in error and fails to establish a *prima facie* case of obviousness of independent claim 33. Accordingly, independent claim 33 is submitted to be patentable over the cited references.

In summary, the Appellant submits that a *prima facie* case of obviousness has not been established with respect to the independent claims 1, 13 and 33 in the subject application.

Respectfully submitted,

By:



Brad A. Schepers,
Reg. No. 45,431